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President

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November 19, 2003

The Honorable William M. Thomas
Chairman
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Dear Chairman Thomas:

On behalf of the 1,100 innovators of medical technology we represent and the patients we serve, I want to congratulate you on the agreement you fostered to advance reforms that will provide America's seniors access to 21st Century medical technology. AdvaMed has long supported reforms to modernize the Medicare program, providing beneficiaries with new health care options and ensuring they have access to state-of-the-art medicine, including new lifesaving and life-enhancing medical tests and treatments.

Thanks to your leadership, the 40 million elderly and disabled Americans who rely on Medicare may soon see an end to the long delays of 15 months to 5 years waiting for access to new, FDA-approved medical technologies. AdvaMed would like to take this opportunity to show its support for the Medicare Conference agreement, especially the following major medical technology provisions:

Strict Timeframes in National Coverage Determination Process

To end the long coverage delays that can prevent patient access to FDA-approved technologies, the Medicare conferees' agreement establishes statutory deadlines for CMS to complete and fully implement national coverage decisions: 9 months for decisions made by CMS internally and 12 months for decisions that are referred to the Medicare Coverage Advisory Committee (MCAC) or other outside technology assessment organization.

Adequate Reimbursement for New Inpatient Medical Technologies

Chronic delays in setting adequate reimbursement for new technologies in the inpatient setting significantly restrict hospital adoption of, and patient access to, lifesaving and life-enhancing new medical technologies. Reforms in conferees' agreement provide increased access to breakthrough technologies in the inpatient setting by setting reasonable thresholds for special add-on payments for new technologies.

Increased Access to Breakthrough Clinical Trials

Medicare currently covers routine patient care costs associated with nearly all drug trials, and most medical device trials. However, Medicare does not cover the routine patient care costs of "breakthrough" (Category A) medical device trials. This coverage limitation is a significant barrier to manufacturers—particularly small companies—and to hospitals in determining whether to pursue a clinical trial for a promising new technology. The agreement requires CMS to provide patients with greater access to breakthrough clinical trials by covering routine patient care costs for Category A trials.

AdvaMed Supports Additional Medical Technology-Related Provisions

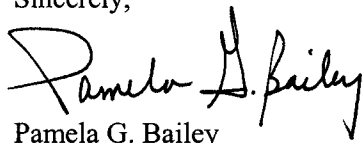
- **Council for Technology and Innovation at CMS.** The Council will coordinate coverage, coding and payment decisions and serve as a single point of contact for patients, physicians and medical technology innovators;
- **Chronic Care Improvement.** These provisions take a dramatic step toward integrating disease management programs and the use of monitoring technologies into traditional Medicare; and
- **Improving Methods for Determining Payment Basis for New Lab Tests.** These provisions specify a process for public notice and comment on the disposition of reimbursement for new clinical laboratory tests.

AdvaMed Opposes Expansion of Durable Medical Equipment Competitive Bidding

Despite the many positive aspects of the conferees' agreement, AdvaMed continues to oppose language that would give CMS broad new authority to enter into competitive bidding contracts to purchase certain products. We believe it is premature to impose competitive bidding on a national scale without fully assessing CMS' limited experience in this area.

Thank you for your hard work in forging this historic agreement, and we look forward to seeing the President sign this bill into law soon.

Sincerely,

A handwritten signature in black ink, appearing to read "Pamela G. Bailey". The signature is fluid and cursive, with the first name "Pamela" being the most prominent part.

Pamela G. Bailey